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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/954,772	09/30/92	ENGELHARDT	D ENZ-5 (D8) (C)

18N1/0609
ENZO DIAGNOSTICS INC.
C/O ENZO BIOCHEM, INC.
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NEW YORK, NEW YORK 10017

MARSCHER EXAMINER	
ART UNIT	PAPER NUMBER
1807	11

DATE MAILED:

06/09/94

NOTICE OF ABANDONMENT

This application is abandoned in view of:

- ☒ Applicant's failure to respond to the Office letter, mailed 11-5-93.
 - ☐ Applicant's letter of express abandonment which is in compliance with 37 C.F.R. 1.138.
 - ☐ Applicant's failure to timely file the response received _____ within the period set in the Office letter.
 - ☐ Applicant's failure to pay the required issue fee within the statutory period of 3 months from the mailing date of _____ of the Notice of Allowance.
 - ☐ The issue fee was received on _____.
 - ☐ The issue fee has not been received in Allowed Files Branch as of _____.
- In accordance with 35 U.S.C. 151, and under the provisions of 37 C.F.R. 1.316(b), applicant(s) may petition the Commissioner to accept the delayed payment of the issue fee if the delay in payment was unavoidable. The petition must be accompanied by the issue fee, unless it has been previously submitted, in the amount specified by 37 C.F.R. 1.17 (l), and a verified showing as to the causes of the delay.
- If applicant(s) never received the Notice of Allowance, a petition for a new Notice of Allowance and withdrawal of the holding of abandonment may be appropriate in view of *Delgar Inc. v. Schuyler*, 172 U.S.P.Q. 513.
- ☐ Applicant's failure to timely correct the drawings and/or submit new or substitute formal drawings by _____ as required in the last Office action.
 - ☐ The corrected and/or substitute drawings were received on _____.
 - ☐ The reason(s) below.

M. Parr 6/9/94
MARGARET PARR
SUPERVISORY PATENT EXAMINER
GROUP 1800

The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 2-44 have been renumbered 240-282, respectively.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title is so broad that it lacks any significant indication as to the claimed invention.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

It is noted that a PTO Form 1449 has been filed 6/28/93 but that it has not been executed nor a copy enclosed since no copies of the references listed thereon have been filed in the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 240-282 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to hybridization conditions that permit hybridization between the probe and target analyte. The broad term "contacting" as cited, for example, in line 3 of claim 240 is not instantly supported beyond hybridization practice. There is no instant disclosure or suggestion for analyte detection other than via hybridization practice as noted above. It is noted also that line 1 of claim 240 is broadly directed to "analyte" detection which is not supported beyond nucleic acid target detection. Also the last line of claim 240 cites the detection via "bound" practice. This also lacks instant support beyond "hybridized" practice. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 275-277 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to antibiotic/bacterium species combinations that are instantly enabled. Not all possible combinations as suggested by these claims are instantly enabled. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 240-244, 254-256, 259-263, 265, 267-273, 278, and 280 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kourilsky et al.

Kourilsky et al. disclose hybridization assay methods using RNA probes labeled with various label types such as disclosed on page 1, line 38-53. Antibody and enzyme label moieties are also disclosed by Kourilsky et al. for example on page 5, lines 18-20. Electron dense labels are disclosed via mercury as given on page 2, lines 47-52. It is noted that instant claim 240 cites Sig moieties linked either to the sugar moiety or phosphate moiety with minimal limitation as to the signal moiety as being detectable. Kourilsky et al. also cite a variety of targets inclusive of genetic diseases, bacterial infections, etc. Taken as a whole Kourilsky et al. reads on the broadly claimed instant invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which

the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 272-277 are rejected under 35 U.S.C. § 103 as being unpatentable over Kourilsky et al. taken in view of Falkow et al.

The instant invention is summarized in the above rejection under § 102(b) and includes the detection of various etiological agents including antibiotic resistance gene targets of various bacteria.

Kourilsky et al. discloses the basics of the instant invention but lacks specific antibiotic resistance gene target detection via hybridization assay but via its generic nucleic acid target disclosure supplies motivation and a reasonable expectation of success for generic nucleic acid targets.

Falkow et al. disclose the detection of various bacterial targets via antibiotic resistance genes disclosed in the abstract as well as the disclosure as a whole.

Thus, it would have been obvious to someone of ordinary

skill in the art at the time of the instant invention to practice hybridization assay detection of etiological agents via the bacterial antibiotic resistance genes because Kourilsky et al. discloses the basic detection methodology and Falkow et al. adds said antibiotic resistance genes of bacteria as nucleic acid targets having a reasonable expectation of success in such hybridization assays.

Claims 240-282 are rejected under 35 U.S.C. § 103 as being unpatentable over Kourilsky et al.

The instant invention broadly is directed to methods using a variety of covalent linkages between a generic "Sig" moiety and hybridization probes used to detect generic targets or wide scope.

Kourilsky et al. discloses the basic hybridization assay using probes labeled in a variety of ways as discussed in the above rejections. It is noted that claim 240 cites "Sig" linkages to every portion of a nucleotide residue only excluding very specific base moiety linkages. This broad "Sig" disclosure permits Kourilsky et al. to suggest Sig moieties that may be as simple as labeled segments of probes which may or may not participate in direct hybridization. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the instant invention given a wide generic set of labels with Sig linked at least at one of the instantly claimed linkages given broad linkages as disclosed by Kourilsky et al.

Ward et al. is cited on the enclosed PTO Form 892 as being of interest in the instant application.

No claim is allowed.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 308-4227 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

AM

A. MARSCHEL:am
November 1, 1993


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